REMARKS

A detailed listing is presented, with appropriately defined status identifiers, for all claims that are or were in the application, irrespective of whether the claims remain under examination. Upon entry of the present amendment, claims 129-147 will be pending.

Additionally, applicants submit with this paper an information disclosure statement, listing a handful of publications made of record in one or another of the present assignee's co-pending applications, all previously cross-referenced in this case. For example, see the Information Disclosure Statements submitted by applicants on April 11, 2002, February 13, 2006, and December 1, 2006, as well as Form PTO-892 attached to the Office Action dated February 25, 2004. None of the listed publications evidences art more relevant, applicants believe, than that already of record here. Both of US 7,186,419 and US 2003/0077244 to Petersen derive from the same provisional application as the present case, while US 6,660,301 to Vogel *et al.* harkens to the same provisional application as does the presently cited Vogel '028 patent, discussed below. International application WO 01/49336 and US 6,486,213 are illustrative of biocompatible-polymer field.

In the wake of a December 9th interview with Examiner Fubara, discussed below, applicants seek cancellation of claims 91-128, without prejudice to or disclaimer, in favor of new claims 129-147. Thus, the latter essentially are redrafted versions of previous claims, particularly including independent claim 116 and its dependent claims.

Support for claims 129-147 can be found in the published specification, US 2003/0077244 A1, as illustrated by the following concordance:

Claim 129:	paragraphs [0013], [0017], [0021], [0023], and [0030], and in Example 2 at paragraphs [0070]-[0073]
Claims 130-133:	paragraph [0018]
Claim 134:	paragraph [0022]
Claim 135:	paragraph [0027]
Claim 136:	paragraph [0036]
Claim 137:	Example 1 at paragraph [0049], and "Preparation 1.3" at paragraphs [0065] and [0066]
Claims 138 and 139:	paragraph [0023]
Claim 140:	paragraph [0030]

Claim 141:	paragraphs [0018], [0019], [0022], [0023], [0027], and [0030]
Claim 142:	paragraph [0034]
Claim 143:	paragraph [0041]
Claim 144:	paragraph [0043]
Claims 145-147:	paragraph [0032]

Accordingly, applicants believe that presentation of the new claims introduces no impermissible new matter, and they request entry of the foregoing changes. Applicants also respectfully request reconsideration of the application in view of the foregoing amendments and these remarks.

Applicants proffer the following statement of the substance of the above-mentioned interview, with some elaboration on the themes discussed with Examiner Fubara:

The undersigned and Mr. Pierre Kary, counsel to the assignee, conducted an in-person interview with the examiner on December 9, 2008. During the interview, the participants discussed the nature of the hydrogels administered in the claimed method of treating urinary incontinence (UI), and how the claimed method was non-obvious over other methods of treatment using polyacrylamide gels in the prior art, *e.g.*, the use of polyacrylamide gels as penile implants, as in the Pavlyk reference (US 5,798,096), and in the treatment of vesicoureteral reflux (VUR), as in the Sknar reference (RU 2148957). These points were illustrated by way of an easel board demonstration, a schematic of which is attached ("Exhibit").

As explained during the interview, the claimed method relies upon administration of a polyacrylamide hydrogel having a certain combination of the physical or rheological properties of rigidity, elasticity, and viscosity that make it effective in treating UI. That is, the recited hydrogel must possess a complex viscosity and an elasticity modulus that fall, respectively, with a certain value range in order for the hydrogel (A) to have a consistency permissive of its being injected into a urethra, as presently recited, and, once injected, (B) to provide sufficient rigidity to bulk the urethra and yet sufficient elasticity to follow the musculature of the urethra, during voiding-related relaxation of the latter, and allow for the passage of urine.

That some balance of these physical properties might yield a polyacrylamide hydrogel suitable for treating UI, pursuant to the claimed invention, was not presaged by the prior art.

Before the invention of the claimed method, in other words, there was no recognition of the required physical properties of a polyacrylamide hydrogel, to achieve the presently recited combination of elasticity and rigidity, in order to produce a hydrogel that would be effective in treating UI when injected into urethra; *i.e.*, an injectable gel that would be rigid when required but also yielding when so required.

For instance, the teachings of Vogel (US 6,335,028), relating UI treatment via injection of polymeric "microparticle" composition (*e.g.*, column 10, lines 40-45), provide no guidance whatsoever on complex viscosity or elasticity modulus, rheological properties of relevance to *hydrogels* but wholly inapplicable to Vogel's *microparticles*.

Annis (US 4,857,041) concerns the placing of solid polyacrylamide material under the urethra, to elevate it. Accordingly, the Annis reference likewise provides no guidance as to the appropriate rheological conditions, regarding complex viscosity and elasticity modulus, for a polymer injected into the urethra to provide bulking and to allow for voiding.

Thus, the skilled artisan would have had no way of predicting whether any combination of physical properties, let alone those presently recited, might render a polyacrylamide hydrogel suitable for treating UI, as claimed. For these reasons, the claimed method of treating UI by injecting into the urethra a polyacrylamide hydrogel of the prescribed properties could not have been obvious to one of ordinary skill.

Furthermore, the Rule 132 Declarations by Diamond and Dmochowski, previously presented, attest that there is no predictability between the anticipation of a utility for a given polymer to treat VUR and the utility of that polymer to treat UI. A different combination of physical properties is required for treatment of these different medical conditions.

Accordingly, applicants submit that the Section 103 rejections previously imposed, now mooted by the cancellation of the rejected claims, are inapposite to the new claim set. Moreover, applicants note that the previous double-patenting rejection, likewise mooted, was over claims of a co-pending application, serial No. 11/469,213, that are directed to a method of treating anal incontinence, which is wholly dissimilar from the method of the newly submitted claims. Applicants therefore submit that no such double-patenting rejection is warranted or sustainable in relation to the new claim set.

In view of the foregoing, applicants believe that the present case is in condition for allowance, and they solicit an early indication to this effect. Examiner Fubara also is invited to contact the undersigned directly, should she feel any issue warrants further consideration.

Respectfully submitted,

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The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.

EXHIBIT

PA / Bulking / Urinary Incontinence (UI)

- Chemical
- Physical (rheological)
  - Turgor (rigidity) — Diamond declaration
  - Elasticity — Dmochowski declaration
  - Viscosity (injectable)

"Impeding urine" (VUR/Sknar) ≢ "Impeding urine" (UI/invention)

PA / Bulking / Prosthesis, etc. — Lessel declaration

- Pavlyk stability testing (no breakdown) — Ankorina-Stark declaration